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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,109	10/01/2001	Cordula Hopmann	02481.1751	4743

7590 06/06/2003

Finnegan, Henderson, Farabow,  
Garrett & Dunner, L.L.P.  
1300 I Street, N.W.  
Washington, DC 20005-3315

EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/06/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/966,109

Applicant(s)

HOPMANN ET AL.

Examiner

Elli Peseselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

The IDS submitted has been considered. However, a copy of 1449 is missing. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the activity of a neurotensin receptor, does not reasonably provide enablement for the treatment of a disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "disease" encompasses all diseases, including cancer and common cold while the specification fails to provide any evidence that the claimed method is useful in the treatment of any specific disease.

Applicant's arguments filed May 5, 2003 have been considered but have not been found persuasive.

The U.S. Patents 5,430,047, 5,250,558 and 5,747,303 have been considered and have been found persuasive with respect to claims 1-19 and 21 but have not been found persuasive with respect to claim 20 which encompasses the treatment of diseases in general. Further, note that said patents fail to provide any evidence antagonists of neurotensin are useful in treating any specific disease.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for citrullimycines, does not reasonably provide enablement for derivatives of citrullimycines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons set forth in the Office Action of February 4, 2003.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" renders the claims indefinite for the reasons set forth in the Office Action of February 4, 2003.

Applicant's arguments filed May 5, 2003 have been considered but have not been found persuasive.

Applicant contends that the term "derivative" is sufficiently defined on pages 9-10 of the specification. This argument has not been found persuasive. The specification states ('derivative') of the compounds according to the invention include compounds derived from a compound of the formula (I) that retain the activity displayed by the compounds of the invention. Said equivalents include, for example, esters, ethers, complexes, or adducts". Note that the definition of "derivative" is not limited to esters, ethers, complexes, or adducts. It is not clear what other derivatives are encompassed by said definition. Further, it would take an undue amount of experimentation to determine what additional derivatives will result in compounds having the activity of the compounds of formula (I).

Claim 22 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grabley et al (U.S. Patent No. 5,252,472) for the reasons set forth in the Office Action of February 4, 2003.

Applicant's arguments filed May 5, 2003 have been considered but have not been found persuasive.

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Applicant contends that the compounds produced by the claimed strain are different from compounds produced by the reference's strain. This argument has not been found persuasive since the same strain under different fermentation conditions can produce different compounds. The data provides by applicant has not been found persuasive since the said data is not part of the specification and has not been presented in verified form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev  
June 4, 2003

  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1800**